# Progress Report

Office of International Health Programs (EH-63), Department of Energy

***Title of Project:*** "RADIATION RISK ASSESSMENT OF CATARACT DEVELOPMENT IN A DOSE-DEFINED COHORT OF WORKERS INVOLVED IN THE CHERNOBYL ACCIDENT"

**Short report covering the sixth funding period**

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***Period covered by this report:*** October 1, 2000 – March 31, 2001

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## *I. Summary of Work*

The Funding Arrangement between the Department of Energy of the United States of America and the Institute of Occupational Health, Academy of Medical Sciences of Ukraine to support the U.S.-Ukraine Cataract Study was signed August 1997. The duration of the entire project period extends from 10.01.97 to 31.12.01. The General Goal of this four-year investigation has been to facilitate the study a 12,000-subject cohort of the Liquidator population.

## *II. Milestones and Deliverables Accomplished during the Reporting Period*

The planned milestones were included in the Annual Work Proposal. All the milestones were addressed during the reporting period. Short summaries of the results are presented in the following sub-sections.

### *A.*

The goals of the work outlined in this 6th month proposal (10.01.00 - 03.31.01) were to:

1) Continue the epidemiological investigations with data acquisition and the second-round exams of 3,000 subjects. Also continuing are the nested Case-control study and a long-term follow-up epidemiology screening with analyses of the dose related ocular effects.
2) Analyze the first and second 3000 subjects from the second round of cohort examinations as they relate to available doses.
3) Input the data from the changes in the epidemiological and new ophthalmological questionnaires as they are generated.
4) Analyze the acquired Case-control data for completeness and compliance.
5) Continue delivering the examination forms for the ophthalmologic investigations.
6) Continue transport of the new changes of the data into the epidemiological database.
7) Continually monitor program progress at the 7 active sites.
8) Confirm list of Liquidator recruits for the 4th year follow-up.
9) Program assessment.

***R***

**Results:**

As shown in Table 1 the second round investigations from October 1, 1999 to September 30, 2000 involved 6159 subjects. During the reported period 2901 subjects were examined. In total, 9060 subjects were examined.

Table 1. Summary of second round of the cohort study during the period October 1, 1999 to March 31, 2001.

| Region | Second round examination at the sites and in the Institute from October 1, 1999 to September 30, 2000. | Second round examination at the sites and in the Institute from October 1, 2000 to March 31, 2001. |
|---|---|---|
| Kharkiv | 520 | 540 |
| Poltava | 1384 | 189 |
| Zaporizja | 12 | 45 |
| Donetsk | 464 | 523 |
| Dnipropetrovsk | 2344 | 1235 |
| Kiev | 1285 | 207 |
| Slavutich | 34 | 27 |
| Atomic workers | 116 | 135 |
| Total | 6159 | 2901 |

Epidemiological data from 4113 completed forms were received during the initial stage of the Case-control study. Following exclusions due to confounders the total cohort numbers 2392 subjects (see Table 2).

Table 2. Summary of the initial phase of the Case-control study during the period April 1, 2000 to September 30, 2000.

| Region | Number of completed Case-control from April 1, 2000 to September 30, 2000. | Number of subjects selected in the two samples (ILL/NOT ILL) of the Case-control investigations | Number of "cases" in the Case-control investigations | Number of "controls" in the Case-control investigations |
|---|---|---|---|---|
| Kharkiv | 351 | 47 | 13 | 34 |
| Poltava | 459 | 63 | 19 | 44 |
| Zaporizja | 3 | 3 | 0 | 3 |
| Donetsk | 232 | 7 | 1 | 6 |
| Dnipropetrovsk | 1816 | 1251 | 632 | 619 |
| Kiev | 1219 | 1004 | 519 | 485 |
| Slavutich | 24 | 13 | 9 | 4 |
| Atomic workers | 9 | 4 | 3 | 1 |
| | | | | |
| Total | 4113 | 2392 | 1196 | 1196 |

As of March 31 as shown in Table 3, 458 Case-Control forms from were added to the study cohort. This was done because the number of subjects in both subgroups diminished due to a variety of factors. The factors include surgical intervention, mortality, morbidity and shifting of some subjects from the control category to the case category. The last column of Table 3 lists those who were reclassified as cases during the previous 6 months.

Table 3. Summary of the completed Case-control forms in the study and number of new cataracts appearing in the "controls" cohort during the period from October 1, 2000 to March 31, 2001

| Region | Number of additional completed examinations Case-control forms included in the Institute Data-Base from October 1, 2000 to March 31, 2001. | Number of the "case" subjects derived from "controls" in the Case-control investigations |
|---|---|---|
| Kharkiv | 51 | 4 |
| Poltava | 45 | 3 |
| Zaporizja | - | 1 |
| Donetsk | 23 | 1 |
| Dnipropetrovsk | 180 | 11 |
| Kiev | 129 | 4 |
| Slavutich | 21 | 1 |
| Atomic workers | 9 | 1 |
| Total | 458 | 29 |

The distribution of the subjects selected for the "Case-Control" study is provided in Table 4. Columns 4 and 5 consist of those subjects comprising the final makeup of the cohorts.

Table 4. Summary of the changes from the initial Case-control study during the period October 1, 2000 to March 31, 2001.

| Region | Number of subjects excluded from the "cases" cohort | Number of subjects excluded from the "controls" cohort | Number of "cases" selected and analyzed | Number of controls" selected and analyzed |
|---|---|---|---|---|
| Kharkiv | 11 | 10 | 17 | 207 |
| Poltava | 9 | 4 | 22 | 199 |
| Zaporizja | 1 | - | 1 | 2 |
| Donetsk | 7 | 10 | 8 | 189 |
| Dnipropetrovsk | 23 | 15 | 539 | 989 |
| Kiev | 17 | 3 | 522 | 630 |
| Slavutich | 2 | 4 | 10 | 23 |
| Atomic workers | 2 | 5 | 4 | 9 |
| | | | | |
| Total | 72 | 51 | 1350 | 1350 |

*C.*

***III. Other relevant information***

The principal US investigator, B.V. Worgul, traveled twice to Kiev during the period 10/01/00 - 03/31/01. The purposes of the trips were to meet with the primary team, discuss logistics for accelerating procedures to allow us to get as closely back on schedule as possible..

Liquidators who were among of the potential candidates from the State Chernobyl Registry (SCR) of Ukraine were included in the second round cohort. Among these were individuals with preliminary estimated doses but who failed to respond to the initial mailings. The advantages of approaching those individuals are a reduction in the biased "enrichment" of the cohort while at the same time increasing the recruitment rate. We received the doses from the Safety Department of the energy generated company "ENERGOATOM" Co. Ministry of Energy of Ukraine of all the nuclear plant workers who are included in the cohort-study. As a result of this experience, the Ministry of Public Health of Ukraine is in the final stages of preparing a formal Order. It will declare that all nuclear workers in Ukraine must be monitored in accordance with the recommendations of the NATO ARW "Ocular Radiation Risk Assessment in Populations Exposed to Environmental Radiation Contamination" in 1997. Those recommendations are based for the most part on the protocol developed in the context of the DOE funded UACOS. The end result will be the ready availability of a large population of current and past workers for radiation related health follow-ups.

During the reporting period, our Ophthalmologist-Investigators were brought to the Institute for quality assurance re-evaluation. Also for this reason members of the project team visited the sites.

There were no obstacles in our portion of the project. Nor were there any unexpected costs.

Because the ERERL has lost funding during much of this review period we began to assume the task of data entry. However this comes at a potential scientific associated with changing in midstream the analytical mode. This is why we planned in the ERERL's task report for the upcoming year was the validation of the consonance of data we assess with that which emanates from the American side. It is necessary to determine if the previously assessed data in the US can be appended to these, our more recent efforts and that together both sides can conduct data entry jointly. This we planned to do in a very intense and specific way to be sure that we do not lose the data from the first and early second observations.

As more of the data-entry tasks are moved to Kiev there will be an increasing cost in personnel to the project. Already we have invested in the Hardware/software to be able to scan the forms automatically. Our US Director Prof. Worgul in consultation with Ukrainian Director, Kundiev, had outlined a sound and critically unassailable approach as was presented in Prof. Worgul's annual report to the DOE. We fear that all which has been done to date will be lost without making provision for an acceptable basis of transition from an exclusively U.S.-based analyses to both US and Ukrainian based analyses. This will be a preamble to the possibility of the entire study becoming a totally Ukrainian effort with direct oversight by the agencies interested in continuing to assess the adverse health consequences of the Chernobyl exposures.

Prof. Worgul at the very beginning felt that efficiency and cost would have been greatly served if we could be the primary analytical component but insecurities' on DOE's side about our capabilities required the exclusive analyses of the raw data by US investigators. That decision has cost us, in time, efficiency and money. Prof. Worgul knows the problems and feels that with the proper protocols and efforts remainder of this funding year can serve to move the study to Kiev in its entirety. The result would be a great savings needed funds and an enormously cost effective way to continue this historic and successful effort.

The goals of the work outlined in this 9th month future proposal (01.04.01 - 12.31.01) are to:

10) Continue the epidemiological investigations with the data acquisition and second round follow-up of the forth 3,000 subjects with the immediate aim of continuing the nested Case-control study and long-term follow-up epidemiology screening with analyses of the dose related ocular effects.
11) Analyze of the first, second and third 3000 subjects from the second round of cohort examinations as they relate to available doses.
12) Input the data from the changes in the epidemiological and new ophthalmological questionnaires as they are generated and data acquisition.
13) Analyze the acquired Case-control data for completeness and compliance.
14) Continue delivering of the examination forms for the ophthalmologic investigations.
15) Continue transport of the new changes of the data into the epidemiological database.
16) Continually monitor program progress at the 7 active sites.
17) Participate list of Liquidator recruits for the forth year re-examination.
18) Participate in the International Conference in New-York (USA).
19) Program assessment.

## *IV. Publications and Preprints*

Ruban A.N. The occupational-induced cataract in Chernobyl Liquidators. – Manuscript. Dissertation for the scientific degree of the Candidate of Medical Sciences on speciality 14.02.01 – Hygiene. - Institute for Occupational Health Academy of Medical Sciences of Ukraine, Kyiv, 2001.

Signatures:

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